

Attorney Docket No. P67772US1
Application No. 10/509,950

Remarks/Arguments:

Claims 1-26, are pending.

The instant amendment adds the wording "isolated" in order to discriminate the subject matter of the claims 8-10 over proteins just existing in nature.

Under item 8 the Office Action rejects the claims 1-10 and 13-20 as being either not supported by a specific and substantial credible asserted utility or well-established utility. The rejection addresses the protein used in the invention as an "orphan protein". However, with all due respect, this is not true. The utility of the "TARPP" is based on the disclosed differential expression of the protein TARPP in patients suffering from Alzheimer's disease (AD) compared to healthy controls (cf. page 5, first full paragraph and Figures 2 and 3).

Thus, TARPP is associated with the neurodegenerative disease AD. The differential expression of TARPP has been proved by quantitative RT-PCR (cf. page 28, bottom). The finding as identified, disclosed and confirmed relation of gene/protein (TARPP) and disease (AD) is an invention and shows clearly its utility. For example, the invention teaches the use of TARPP as a diagnostic marker for neurodegenerative diseases, in particular AD, which is performed by determination and comparison of the level of TARPP in AD patients and healthy controls (Figures 2, 3, Tables 1 and 2). Tables 1 and 2 show unequivocally that the level of TARPP protein in a AD patients is higher than the level in control individuals (Table 1: control level 0.47-1.39, patients level 1.34-4.11; Table 2: control level 1.1-1.76, patients level 1.21-5.51). This means TARPP can be

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utilized as a marker, i.e., diagnostic tool. Furthermore, the use of TARPP as a screening target is disclosed on page 22, bottom until page 24.


The double-patenting rejection claims 9 and 10 cannot be maintained. A diagnostic method of course is completely different from a screening method, due to the fact that the results obtained are different. A diagnostic method is employed in order to elucidate whether a patient is suffering from a disease and a screening assay is employed in order to obtain and identify drugs interacting with a target. Only in the case that a skilled person would, but of course he would not, understand a screening method as "a molecular diagnostic" method, one could further think about the argument proposed concerning double-patenting. However, applicant submits that the two methods described in the different claims are sufficiently distinct.

Favorable action is requested.

Respectfully submitted,

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